X. SAFETY AND EFFECTIVENESS SUMMARY

Medtronic Neurosurgery INVISx™ Burr Hole Lock

K013000

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number: 2021898

DEC 0 5 2001

Address of Manufacturer: Medtronic Neurosurgery
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1773
Fax: (805) 968-5038

Contact Person: Janet McAuley

Date: August 28, 2001

Trade or Proprietary Name: Medtronic INVISx™ Burr Hole Lock

Common, Usual or Classification Name: Burr Hole Cover (21 CFR 882.5250)

Predicate Device Identification:
Medtronic INVISx™ Cranial Fixation System (K010361).

Device Description:
The INVISx™ Burr Hole Lock consists of a two piece polymer implant used to cover the burr hole(s) created during cranial surgery.

INVISx™ Burr Hole Lock is packaged sterile and is intended for single (one-time) use only.

Intended Use:
The INVISx™ Burr Hole Lock is intended for use in covering burr holes and in refixation of cranial bone flaps following a craniotomy.

Intended Use of Predicate Device:

The INVISx™ Cranial Fixation System is intended for use in refixation of cranial bone flaps after a craniotomy.

Technological Comparison:
The INVISx™ Burr Hole Lock is equivalent to the Medtronic INVISx™ Cranial Fixation System (K010361). Substantial equivalence is based upon materials, design, performance specifications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Janet McAuley
Regulatory Specialist
Medtronic Neurosurgery
125 Cremona Drive
Goleta, California 93117

DEC 0 5 2001

Re: K013000
Trade/Device Name: Medtronic INVISx™ Burr Hole Lock
Regulation Number: 21 CFR 888.5250 and 21CFR 888.5330
Regulation Name: Burr hole Cover and Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXR and GXN
Dated: August 28, 2001
Received: September 6, 2001

Dear Ms. McAuley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: INVISx™ Burr Hole Lock 510(k) Number (if known): K013000

The INVISx™ Burr Hole Lock is intended for use in covering burr holes and in refixation of cranial bone flaps following a craniotomy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use: _____
or
Prescription Use: X
(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013000